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Effectiveness of totally tubeless percutaneous nephrolithotomy in selected patients: a prospective randomized study

Mustafa Okan Istanbulluoglu · Bulent Ozturk · Murat Gonen · Tufan Cıcek · Hakan Ozkardes

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Abstract
Objectives Compared with the standard technique, the number of percutaneous nephrolithotomy (PCNL) operations without a drainage catheter is increasing in recent years. In this prospective randomized study, we compared the morbidity of totally tubeless (tubeless and stentless) PCNL operations with the standard operation technique in a single center with a selected patient population.
Methods Ninety patients who fulfilled the criteria were included. Forty-five patients underwent totally tubeless PCNL (Group 1) and a 14F malecot nephrostomy catheter was used in another set of 45 patients (Group 2). Inclusion criteria for the study were no serious bleeding or perforation in the collecting system during the operation, stone free or clinically insignificant residual fragments (CIRF <4 mm), and no more than one access.
Results When two groups were compared with regard to age, stone volume, postoperative hemoglobin change, transfusion rate, and operation time, no significant differences were found between the two groups. However, a significant difference was found in hospitalization time between the two groups ($P < 0.05$). The amount of non-steroidal analgesic (tenoxicam) needed and non-steroidal analgesia-resistant pain which was resolved with narcotic analgesics (meperidine) were significantly lower in Group 1 ($P < 0.05$). Complications were observed in two patients (4.5%) in Group 1 (one retroperitoneal hematoma, one long-lasting renal colic) and in six patients (13.3%) in Group 2 (five prolonged urine drainage, one long-lasting fever) ($P < 0.05$).
Conclusions Tubeless and stentless PCNL is a safe method and reduces hospitalization time and analgesic requirement, and promotes quality of life in selected patients.

Keywords Percutaneous nephrolithotomy · Stone disease · Tubeless

M. O. Istanbulluoglu (✉) · B. Ozturk · M. Gonen · T. Cıcek · H. Ozkardes
Department of Urology, Baskent University School of Medicine, Selçuklu, 42060 Konya, Turkey
e-mail: drokanist@yahoo.com

Introduction

In the surgical treatment of urinary stone disease, open surgery has been superseded by percutaneous nephrolithotomy (PCNL) in recent years. Nephrostomy catheters with different diameters are used after standard PCNL operations to provide renal drainage and to tamponade bleeding [1, 2].

However, in the early postoperative period there are concerns about nephrostomy catheters with regard to pain and prolonged hospital stay [3, 4]. For that reason in recent years, new modifications have been described in PCNL operations, for example use of an

external ureter catheter or J-stent instead of nephrostomy catheters to reduce complaints caused by the catheter; this has since become known as tubeless PCNL [1, 2]. Also in a limited number of studies in the literature, no ureter stents have been implemented; this is called totally tubeless PCNL [3–12].

In this study we compared the morbidity of totally tubeless PCNL operations with the standard operation technique in a selected patient population.

Material and methods

Of 253 patients who underwent PCNL at our clinic between Jun 2005 and July 2007, 90 patients who met the inclusion criteria were enrolled in this study and randomized to two groups. Inclusion criteria were no serious bleeding or perforation in the collecting system during the operation, stone free or CIRF (<4 mm) at the end of the procedure, no more than one access, and no major arterial bleeding. Patients with staghorn stone, solitary kidney, or kidneys with congenital anomalies and those who had undergone bilateral simultaneous PCNL were excluded from the study. Local ethics committee approval was obtained for the study.

Before the operation, complete blood count, serum creatinine level, and urine culture were performed. Radiological evaluation was performed with ultrasonography and intravenous pyelography, and, in a limited number of patients, with non-contrast computerized tomography. Under general anesthesia with the aid of cystoscope, a 7F ureter catheter was placed into the ipsilateral ureter and the catheter was then attached to the urethral Foley catheter. The patient was then positioned in the prone position. All percutaneous accesses were performed in the prone position. Access to the selected calyx was performed with the aid of C-armed fluoroscopy and an 18-gauge needle. After entry of the collecting system with a guide wire, dilatation was performed with Amplatz dilatators and a 30F Amplatz sheath was placed, through which a 26F rigid nephroscope was inserted and fragmentation of the stone was carried out with pneumatic lithotripter.

At the end of the operation, stone-free patients and patients with CIRF (<4 mm) were determined fluoroscopically and antegrade pyelography was performed to evaluate the collecting system. Ureter catheters were removed immediately after the operation and the urethral foley catheters were removed from all patients the following day.

Patients were randomized into two groups in the operating room upon completion of the procedure by means of a systematic sampling technique. No catheter was inserted into 45 patients in Group 1 (the previously inserted 7F ureter catheters were removed after the operation) whereas standard 14F nephrostomy catheters were placed in 45 patients in Group 2, which were then monitored by antegrade pyelography. Hemoglobin levels were checked in all patients 16 h after the operation and if there was any doubt about perinephric collection, ultrasonography was performed. The decision to remove the nephrostomy catheters in Group 2 was made on the basis of urine color. Antegrade pyelography was performed before removal of nephrostomy catheters.

Age, stone diameters, operation time, post-operative hemoglobin change, complication rate, blood transfusion rate, analgesic need, and hospitalization time were compared between the groups.

Differences in percentages (qualitative variables) were analyzed by use of the χ^2 test. Differences between means were evaluated with Student's t test and the Mann–Whitney U test. Statistical analyses were performed using SPSS 15.0. A P value <0.05 was considered to be statistically significant.

Results

The totally tubeless group (Group 1) consisted of 25 male and 20 female patients, while the standard PCNL (Group 2) consisted of 24 male and 21 female patients. Mean patient age in Groups 1 and 2 were 47.48 ± 13.04 (range 27–83) and 43.91 ± 14.44 (range 19–77) years, respectively ($P = 0.42$).

Stones were located in the lower calyx ($n = 26$), pelvis ($n = 11$), multiple calyces ($n = 6$), upper ureter ($n = 1$), and upper calyx ($n = 1$) in Group 1; and in the lower calyx ($n = 14$), pelvis ($n = 19$), multiple calyces ($n = 10$), and upper ureter ($n = 2$) in Group 2. Supracostal access (between the 11th and 12th ribs) was performed in five patients in Group 1 and in six patients in Group 2 ($P = 0.35$). No significant changes were found between the groups in terms of mean stone volume, operation time, hemoglobin level change, and transfusion rates (Table 1). However, mean hospitalization time was significantly

shorter in Group 1 than in Group 2 ($P < 0.05$). Complications were encountered in two (4.4%) and six (13.3%) patients in Groups 1 and 2, respectively ($P < 0.05$) (Table 1). One patient in Group 1 had severe analgesic-resistant pain, which was resolved immediately after insertion of a J-stent catheter. Another patient in Group 1 developed perirenal collection and this was managed by insertion of a drainage tube under tomography guidance. In the standard PCNL group, prolonged urine drainage was seen in five patients; this was resolved by insertion of a J-stent catheter. One patient suffered from high fever (>38.5°C) and was treated with intravenous antibiotics.

Non-steroidal analgesics (tenoxicam) were administered to the patients at a dose of 20 mg intramuscularly (i.m.) (maximum 40 mg). If this was not effective, intramuscularly meperidine was administered. During the early postoperative period (the first 24 h) five patients (11.1%) in Group 1 did not require any analgesics whereas all patients in Group 2 required analgesics, showing that tubeless PCNL reduces the analgesic requirement significantly ($P < 0.05$) (Table 2).

Discussion

The objective of the PCNL operation is to cure patients with renal and upper ureteral stones with minimal morbidity and hospital stay. In recent years, this method has become a routine procedure, with minimal morbidity and complication rates and decreased hospital stay compared with the open

Table 1 Patient characteristics

	Totally tubeless PCNL Group 1 ($n = 45$)	Standard PCNL Group 2 ($n = 45$)	P value
Age (Year)	47.48 ± 13.04	43.91 ± 14.44	0.42*
Stone size (mm^2)	448.93 ± 249.13	453.35 ± 165.97	0.46**
	430 (range 125–1,350)	432 (range 130–1,200)	
Hospitalization time (day)	2.11 ± 1.13	3.48 ± 1.68	0.01**
	2 (range 1–7)	2 (range 1–6)	
Operation time (min)	52.55 ± 22.95	64.11 ± 18.68	0.13**
	50 (range 20–80)	57.5 (range 25–75)	
Postoperative hemoglobin drop (gr/dl)	1.59 ± 0.96	1.63 ± 1.01	0.06**
	1.40 (range 0.30–3.70)	1.20 (range 0.20–3.60)	
Blood transfusion (n)	2 (4.4%)	3 (6.6%)	0.64***
Supracostal access (n)	5 (11.1%)	6 (13.3%)	0.35***
Complication rate (n)	2 (4.4%)	6 (13.3%)	0.002***

Results are given as mean ± SD, as median (min–max), and as percentages

Emboldening is used to emphasize the significance of the P values

*t test

**Mann Whitney U test

***χ^2 test

Table 2 Analgesia requirements in the totally tubeless and the standard PCNL groups

Analgesic need	Totally tubeless PCNL Group 1 ($n = 45$)		Standard PCNL Group 2 ($n = 45$)		P value*
	n	%	n	%	
Non-steroidal anti inflammatory analgesics (tenoxicam)					
0	5	11.1	0	0	0.02
20 mg	22	48.9	17	37.9	
40 mg	18	40.0	28	62.1	
Narcotic analgesics (meperidine)					
0	30	66.7	22	48.9	0.004
50 mg	12	26.7	17	37.9	
100 mg	2	4.4	4	8.8	
150 mg	1	2.2	2	4.4	

*χ^2 test

technique. Hospitalization time can be decreased by avoiding nephrostomy tube insertion. In a wide spectrum of studies, this was achieved with J-stent or ureteral catheter insertion in order to maintain the drainage [1, 2, 13–18]. In this kind of procedure patient selection is vital. But according to some authors, tubeless PCNL with stent will be the standard procedure in the future [14, 15].

Rana et al. performed tubeless PCNL on 110 patients and the ureter catheter, which was inserted preoperatively, was removed 16–20 h after the operation [14]. Patient selection criteria were not strict and the procedure was carried out on 12 patients with renal failure, 18 patients with previous renal surgery, and seven patients with a solitary kidney. After the operation, perirenal hematoma was observed in 18 patients and it was mostly managed conservatively, although one patient with retroperitoneal hematoma had undergone re-operation. Transfusion was required in six patients only. It was concluded that a nephrostomy tube was unnecessary for any type of patient after the PCNL operations [14].

In another study, Al-Ba'adani et al. reported that tubeless PCNL was effective in 121 patients and insertion of a ureter catheter was sufficient for drainage; the complication rate was 9.9% [15]. They pointed out that tubeless PCNL is a new gold standard technique. Similar groups of studies have also showed that tubeless PCNL is an effective method with decreased pain and hospital stay [1, 2, 14, 15]. However the ureteral stents can cause irritative voiding symptoms, for example dysuria and pollakuria, and removal of the stent at a later time results in additional morbidity for the patient. For this reason we offer totally tubeless PCNL to a selected group of patients.

In the literature, tubeless PCNL studies are reported but only a few are totally tubeless PCNL. Totally tubeless PCNL was first described by Wickham et al. in 1984 [5]. They reported a mean hospital stay of 2.8 days, and infection and bleeding requiring transfusion was observed in 10% and 22% of the patients, respectively. They concluded from these results that tubeless PCNL could be applicable. But the number of patients with totally tubeless was unclear in their study [5]. In contrast, two years after this study, Winfield and colleagues showed that totally tubeless PCNL prolongs hospital stay with an increase in complication rates [6]. After that discouraging study, totally tubeless PCNL operations were interrupted till 1997 when Bdesha showed that tubeless PCNL is a safe procedure with minimal morbidity [7].

Karami et al. compared 30 totally tubeless patients with 30 standard PCNL [4]. Hospital stay and the need for analgesics in the totally tubeless group were comparable with those for the standard PCNL group. No transfusion was required and serious complications were not seen in either group [4]. Aghamir et al. reported similar results in their series of 43 patients [3].

With developing technology, hemostatic agents are being used after PCNL operations to avoid bleeding and extravasations. With wide use of these materials, the number of tubeless procedures has increased [16, 17]. The only study with anticoagulant agents to avoid bleeding after totally tubeless PCNL is that of Aghamir et al. [10]. Twenty patients were treated with totally tubeless PCNL and the nephrostomy tracts were sealed with Surgicel (oxidized cellulose) in ten patients and left unsealed in another ten. When the two groups were compared with regard to decrease in hematocrit level, no significant difference was found [10]. On the other hand, anticoagulant agents have the potential to aggregate in the collecting system. So, some investigators recommend the use of occlusion catheters, which would be an additional cost for the procedure [17, 18]. In our study, we did not use any hemostatic agent as we have not encountered any major bleeding preoperatively.

Gupta et al. performed totally tubeless PCNL on 96 patients with symptomatic lower calyx stone <1 cm that are resistant to extracorporeal shock wave lithotripsy [8]. All patients were stone free with minimal morbidity and shorter hospital stay, because of minimal instrumentation of the ureter and no ancillary procedures, for example stent removal. One patient required J-stenting for substantial leakage from the PCNL site, and was improved with conservative management.

Karami et al. compared tubeless PCNL with ureteroscopy in patients with impacted stones of the upper ureter >1 cm [9]. In mild and severe hydronephrosis, blind access was performed. Stone free rates for the totally tubeless group and for ureteroscopy was 94.3% and 51.4%, respectively. No serious complications were seen in either group. In another

study, totally tubeless PCNL was performed in uncomplicated cases with intact pelvicaliceal system; there was no significant bleeding or residual stone [12]. Mean hospital stay was 2.9 days. Four patients with horseshoe kidneys were also included. They reported hydrothorax in a patient with horseshoe kidney in whom the upper pole approach was used. Severe sepsis, postoperative bleeding, and blood transfusion were also reported for another patient with horseshoe kidney. Long hospital stay and increased complication rates for horseshoe kidneys prompted us to select the patients carefully. Horseshoe kidneys, especially, and other location anomalies generally occur with renal artery or vein anomalies.

In the current study, our findings are similar to those in previously reported studies. We believe that totally tubeless PCNL can be performed safely in selected patients when there is no major bleeding or perforation in the collecting system, no residual stone fragments, or no congenital anomalies. Analgesia requirement is significantly less than for the standard technique. Postoperative prolonged pain in this group of patients might be because of undetectable residual stone fragments or clots in the ureter.

Conclusions

Totally tubeless PCNL is effective in a selected patient population, with less analgesia requirement, and decreased complication rates and hospital stay. We believe that with experience and careful patient selection, normal peristaltic ureter is the best drainage tube.

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